IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
STATESVILLE DIVISION

RAMONA WINEBARGER and REX WINEBARGER,
Plaintiffs,

CASE NOS. 5:15CV57-RLV; 3:15CV211-RLV

v.
BOSTON SCIENTIFIC CORPORATION,
Defendant

MARTHA CARLSON,
Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION
Defendants

PLAINTIFFS OBJECTIONS AND COUNTER DESIGNATIONS TO DEFENDANT BOSTON SCIENTIFIC'S DEPOSITION DESIGNATIONS OF ROBERT MIRAGLIUOLO TAKE ON APRIL 24 AND 25, 2013

BSC Designations	Objection	Plaintiffs Counter Designation
rm042413, (Pages 52:2 to 53:10) 52 (Exhibit Number 141 marked for identification) Q. This is a document that is entitled "Guidance for Preparation of a Premarket Notification Application for a Surgical Mesh." Correct? A. Correct. Q. And it's a guidance for industry and/or for FDA reviewers, staff and/or compliance. Correct? A. Correct. Q. This is not the first time you've seen this document. Right? A. Correct. Q. And what's the date of the document? A. March 2nd, 1999.	52:2-53:10 FRE 401, 402, 403 FDA Reference	

16 Q. What is the purpose of this kind of a document? 17 A. This is called a special controls under the 18 Class II regulations, and it's to provide guidance to 19 industry, the FDA reviewers, and FDA compliance on what 20 types of information industry should provide and FDA 21 should be looking for to assess a premarket notification 22 application for surgical mesh product. 23 Q. Put in an even more concise manner, it's FDA 24 telling you if you want a product cleared, this is what 53 1 you need to send us. 2 A. It's a guidance on it, yes. 3 Q. Right. 4 A. Correct. 5 Q. It helps you. You look at this document and 6 you know what to send the FDA to try and get a product 7 cleared. Right? 8 A. Correct. 9 Q. So they're kind of telling you what they want? 10 A. Correct.		
rm042513, (Page 455:10 to 455:16) 455 10 Q. Generally speaking, Rob, describe for the jury 11 how many medical devices containing pelvic mesh have 12 been cleared by the FDA in the period of time that you 13 have been the vice president of regulatory for Boston 14 Scientific. 15 A. I think it's approximately nine different 16 products have been cleared.	455:10-16 FRE 401; 402; 403 FDA Reference	
rm042513, (Pages 456:16 to 457:14) 456 16 Q. Okay. Earlier yesterday there was a document 17 that was marked and identified as Exhibit 141, which is 18 entitled "Guidance for the Preparation of a Premarket	456:16-457:14 FRE 401, 402, 403 FDA Reference	

19 Notification Application for a Surgical Mesh." 20 And I don't want to spend too much time on 21 this, but just give the jury some sense for what is the 22 importance of this guidance document from the FDA for 23 purposes of a company like Boston Scientific seeking FDA 24 clearance for products containing surgical mesh. 457 1 A. This is a guidance document. It is considered 2 a special controls under the regulations. And it's for 3 Class II products whose pathway to market is the 510(k). 4 And this is a document that basically lays out 5 the information that FDA -- not only the FDA should ask 6 but also the guidance for industry to provide the 7 appropriate information that FDA feels is necessary for 8 them to make the decision to allow the product to be on 9 the market. 10 Q. And where does the safety and efficacy of the 11 product factor into those guidelines? 12 A. It factors into their substantial equivalence 13 statement in that this information is sufficient for 14 them to make that determination.		
rm042513, (Page 466:6 to 466:19) 466 6 Q. I want to mark quickly one more document. I'll 7 mark this as Exhibit 195. 8 (Exhibit Number 195 9 marked for identification) 10 Q. And this is a different group. This is the 11 American Urogynecologic Society. 12 This exhibit states that "The American 13 Urogynecologic Society is a nonprofit organization of 14 over 1,500 physician and allied health members. AUGS 15 represents the largest professional society representing	466:6-19 Foundation, Cumulative, FRE 403; Hearsay	

16 Female Pelvic Medicine and Reconstructive Surgery 17 specialists." 18 Do see where I read that in the second 19 paragraph?		
rm042513, (Pages 466:22 to 467:2) 466 22 Q. What is the position as reflected in this 23 position statement of the -- a group called AUGS with 24 respect to the appropriateness of having POP devices 467 1 available for patients who may be appropriate 2 candidates?	466:22-467:2 Foundation, Cumulative, FRE 403; Hearsay	
rm042513, (Page 467:4 to 467:10) 467 4 A. I'll read it. "The American Urogynecologic 5 Society strongly opposes any restrictions by state or 6 local medical organizations, healthcare systems, or 7 insurance companies which ban currently available 8 surgical options performed by qualified and credentialed 9 surgeons on appropriately informed patients with pelvic 10 floor disorders."	467:4-467:10 Foundation, Cumulative, FRE 403; Hearsay	
rm042513, (Pages 472:7 to 473:6) 472 7 Q. Okay. Let's shift gears a little bit. Let's 8 talk about FDA and FDA transparency. The jury may have 9 heard and seen e-mails and meetings and whatnot between 10 you and others on your regulatory team with the FDA. 11 Describe, first of all, the role of the FDA in 12 terms of reviewing our submissions and commenting on 13 them. 14 A. Okay. FDA has a very important, very difficult 15 role in the healthcare system. And one of them is 16 determining which products should be placed into 17 commercialization.	474:7-473:6 FRE 401, 402, 403 FDA Reference	

18 And how it's done is they -- the company 19 provides FDA a body of evidence and quite detailed 20 information. When that body of evidence is submitted to 21 FDA in the form of a 510(k), that review process at FDA 22 is conducted by multiple functions and FDA experts. 23 There's clinical folks, there's medical folks, there's 24 experts in biocompatibility, there's experts in 473 1 sterilization, there's experts in packaging. 2 And all of them review their -- that body of 3 evidence from their perspective. And should they have 4 any questions, they will provide those questions back to 5 the company and provide the company an opportunity to 6 respond to those questions.		
rm042513, (Pages 473:12 to 475:6) 473 12 Q. What input and what kind of regulations govern 13 what is in the directions for use? 14 A. The directions for use are -- is a critical 15 component of any submission to FDA, and it's one of 16 the main methods by which FDA controls devices. 17 So any information that's put into the 18 directions for use has to be reviewed and approved by 19 FDA prior to it being placed into -- alongside the 20 product into commercialization. 21 Q. Let me quickly identify what's been previously 22 marked as a direction for use in the Uphold. I think 23 you've previously identified this. 24 Is that what this appears to be, Exhibit 83? 474 1 A. Yes. 2 Q. And examples of what could be in the directions 3 for use include such things as? 4 A. There's the general caution statement that	473:12-475:6 FRE 401, 402, 403 FDA Reference	

5 states that this product can only be sold or used on the 6 order of a physician. And then you get into the 7 concepts of warnings. Those are explanation of things 8 that the user should be aware of. There's the intended 9 use statement, which is specific use of the product that 10 FDA has cleared. 11 There's a section called contraindications, 12 which are fairly critical. There's areas where it's 13 strongly recommended that the product not be used in. 14 There's another section called warnings and 15 potential complications that gives a long list of 16 potential complications that are possible to occur. 17 Q. Okay. 18 A. And this also provides instructions on how to 19 use the product. 20 Q. When you're talking about the FDA regulating 21 these words, these specific words, these categories of 22 information, contraindications, warnings, intended 23 use, indications for use, those are examples of what 24 you're talking about? 475 1 A. Yes. 2 Q. And we have examples here where our submissions 3 to the FDA invited comments and suggestions and 4 requested changes from the FDA on the terms of such 5 things as the directions for use? 6 A. Correct.		
rm042513, (Page 480:1 to 480:4) 480 1 Q. Counsel was -- he asked you a number of 2 questions about informed consent. Do patients and 3 doctors have sources of information about products and 4 about conditions and about surgery options?	480:1-13 FRE 402, 403,403, Foundation	
rm042513, (Page 480:6 to 480:13)	480:1-13	

480 6 A. Absolutely, yes. 7 Q. Let's talk about doctors. What are sources of 8 information to doctors in addition to the directions for 9 use that we've just identified? 10 A. There is the literature. There's also various 11 society -- medical societies that they can obtain 12 additional information from. And there's also the 13 Internet, which also has a wealth of information on it.	FRE 402, 403,403, Foundation	
rm042513, (Page 507:4 to 507:19) 507 4 Did Boston Scientific know and follow the 5 regulatory rules to demonstrate the safety and 6 effectiveness of its pelvic mesh products? 7 A. Yes. 8 Q. Did the FDA review the scientific evidence, 9 review your testing to reach a conclusion as to whether 10 or not we had met the standards? 11 A. Yes. 12 Q. Are there many occasions of the FDA requesting 13 meetings, having calls, sending us letters, sending us 14 e-mails, asking for additional information on a whole 15 variety of topics related to our pelvic mesh products? 16 A. Yes. 17 Q. And in every case the submissions that we made 18 were ultimately cleared by the FDA? 19 A. Yes.	507:4-19 FRE 401, 402, 403 FDA Reference	

1. **Objections to Designated Exhibits**
   a. Plaintiffs object to Miragliuolo 141 under FRE 401, 402, and 403 as the exhibit is an impermissible FDA reference.
   b. Plaintiff object to Miragliuolo 195 under FRE 401, 402, 403 and 802 as the document contains FDA references and out-of-court statements from a group the witness is not a member of.

DATED: June 26, 2015 Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on June 26, 2015, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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